K110274

510(k) SUMMARY

JUN 10 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

The Assigned 510(k) Number is:

Date: January 26, 2010

Submitted by:	Wallac Oy, subsidiary of PerkinElmer 940 Winter Street Waltham, MA 02451 USA
Contact Person: Primary:	Susan K. Hamann Tel: 781-663-5872 Fax: 781-663-5983
Secondary:	Kay A. Taylor Tel: 317-418-1735 Fax: 317-536-3064
Trade Name:	AutoDELFIA® Neonatal IRT kit B005-212, B005-204
Common Name: Regulation:	AutoDELFIA Neonatal IRT kit 21 CFR 862.1725
Classification Name:	Trypsin Test System and Electrode
Product Code:	JNO
Predicate Device:	AutoDELFIA® Neonatal IRT kit, B005-112 510(k) Number (K0003668)

Device Description:

The AutoDELFIA Neonatal IRT assay is a solid phase, two-site fluoroimmunometric assay based on the direct sandwich technique in which two monoclonal antibodies (derived from mice) are directed against two separate antigenic determinants on the IRT molecule. Calibrators, controls and test specimens containing IRT are reacted simultaneously with immobilized monoclonal antibodies directed against a specific antigenic site on the IRT molecule and europium-labeled monoclonal antibodies (directed against a different antigenic site) in assay buffer. The assay buffer elutes IRT from the dried blood on filter paper disks. The complete assay requires only one incubation step.

Enhancement Solution dissociates europium ions from the labeled antibody into solution where they form highly fluorescent chelates with components of the Enhancement Solution. The fluorescence in each well is then measured. The fluorescence of each sample is proportional to the concentration of IRT in the sample.

Intended Use:

The AutoDELFIA Neonatal IRT kit is intended for the quantitative determination of human immunoreactive trypsin(ogen) (IRT) in blood specimens dried on filter paper as an aid in screening newborns for cystic fibrosis using the 1235 AutoDELFIA® automatic immunoassay system.

Substantial Equivalence:

The AutoDELFIA Neonatal IRT kit (B005-212/B005-204) is substantially equivalent to the currently marketed AutoDELFIA IRT kit (B005-112) (K0003668). There are the following similarities and differences between the two kits:

Table 1. Characteristics of the two kits.

Characteristic (Feature)	AutoDELFIA Neonatal IRT kit B005-212/B005-204 (New Device)	AutoDELFIA Neonatal IRT kit B005-112 (Predicate Device)
	Similarities	
Intended User	Adequately trained laboratory personnel in laboratories performing newborn screening	Same
Intended Use / Indications for Use	The AutoDELFIA Neonatal IRT kit (B005-212/B005-204) is intended for the quantitative determination of human immunoreactive trypsin(ogen) (IRT) in blood specimens dried on filter paper as an aid in screening newborns for cystic fibrosis using the 1235 AutoDELFIA® automatic immunoassay system.	The AutoDELFIA Neonatal IRT (B005-112) is intended for the quantitative determination of human immunoreactive trypsin (IRT) in blood specimens dried on filter paper as an aid in screening newborns for cystic fibrosis using the 1235 AutoDELFIA® automatic immunoassay system.
Chemical Principle	The AutoDELFIA Neonatal IRT assay is a solid phase, two-site fluorimmunometric assay based on the direct sandwich technique in which two monoclonal antibodies (derived from mice) are directed against two separate antigenic determinants on the IRT molecule. Calibrators, controls, or test specimens containing IRT are reacted simultaneously with immobilized monoclonal antibodies directed against a specific antigenic site on the IRT molecule and europium-labeled monoclonal antibodies (directed against a different antigenic site) in assay buffer. The assay buffer elutes IRT from dried blood on filter paper disks. The complete assay requires only one incubation step. Enhancement Solution dissociates europium ions	Same

Characteristic (Feature)	AutoDELFIA Neonatal IRT kit B005-212/B005-204 (New Device)	AutoDELFIA Neonatal IRT kit B005-112 (Predicate Device)
	from the labeled antibody into solution where they form highly fluorescent chelates with components of the Enhancement Solution. The fluorescence in each well is then measured. The fluorescence of each sample is proportional to the concentration of IRT in the sample.	
Detection principle	Time-resolved fluorescence	Same
Specimen	Dried blood on filter paper disks with a diameter of approximately 3.2 mm (1/8 inch)	Same
Antibodies	Two different mouse monoclonal antibodies	Same
Calibrator and Control Matrix	Human blood derivative with a hematocrit of 50-55% and spotted onto filter paper (Whatman, no. 903) (Washed blood cells in buffer containing BSA and protease inhibitors) (Filter paper on a supportive frame called "cassette")	Same (Washed blood cells in saline containing saccharose) (Filter paper as sheets)
Kit Calibrators	6 levels. (approx. values 0, 25, 50, 100, 250, 500 ng/mL blood.	Same
Kit Controls	3 levels (approx. values 30, 70 and 110 ng/mL blood)	3 levels (approx. values 40, 70 and 120 ng/mL blood)
Calibration	Calibrated using gravimetric methods (In-house calibrators contain protease inhibitors and BSA item 1.)	Same (In-house calibrators without protease inhibitors, contain BSA item 2.)
Assay buffer	IRT Assay Buffer, ready for use Tris-HCl buffered (pH 7.8) salt solution with bovine serum albumin, and additives.	Same

Characteristic (Feature)	AutoDELFIA Neonatal IRT kit B005-212/B005-204 (New Device)	AutoDELFIA Neonatal IRT kit B005-112 (Predicate Device)
	(BSA item 1 used)	(BSA item 2 used)
Coated Plates	Anti-IRT Microtitration Strips, 8 X 12 wells coated with antibodies directed against a specific site on the IRT molecule (mouse monoclonal)	Same
Tracer	Anti-IRT-Eu tracer stock solution (~50 µg/mL), mouse monoclonal, ready for use. .	Same
Instrument	1235 AutoDELFIA Instrument	Same
Dissociation solution	Enhancement Solution	Same
Expected Values	The measurement of IRT from dried blood spots is used as a means of identifying a population of newborns who are at increased risk of having CF and should be selected for 2nd tier testing. The identification is based on the use of a fixed cut-off value or population percentile. The IRT cut-off levels must be determined by each newborn screening laboratory to meet the desired sensitivity and specificity of the screen and should be evaluated periodically.	Same
Measuring Range	16 to 480 ng/mL blood Linearity Range: 16 to 480 ng/mL blood	4(as defined by LoB) to 500 (as defined by upper calibrator) ng/mL blood Linearity Range: No claims for linearity in labeling.
Analytical Sensitivity / Limit of Blank, Limit of Detection	Limit of Blank 0.53 ng/mL blood Limit of Detection 2.9 ng/mL blood	Limit of Blank < 4 ng/mL blood
Antibody Cross-Reactions in the Assay	α2-macroglobulin < 4 ng/ml blood α1-antitrypsin < 4 ng/ml blood Phospholipase A2 < 4 ng/ml blood Chymotrypsin < 4 ng/ml blood	Same

Characteristic (Feature)	AutoDELFIA Neonatal IRT kit B005-212/B005-204 (New Device)	AutoDELFIA Neonatal IRT kit B005-112 (Predicate Device)
	Human IgG < 4 ng/ml blood Uropepsinogen < 4 ng/ml blood	
Hook effect	No hook effect has been found with IRT concentrations up to 40,000 ng/mL	Same
Precision (Total Variation using a full calibration curve on each plate)	16.7 ng/mL blood CV% 8.7 22.5 ng/mL blood CV% 9.6 48.0 ng/mL blood CV% 9.1 104 ng/mL blood CV% 8.0 247 ng/mL blood CV% 8.3 401 ng/mL blood CV% 8.4 449 ng/mL blood CV% 9.4	42.6 ng/mL blood CV% 9.3 98.8 ng/mL blood CV% 10.0 266 ng/mL blood CV% 9.6

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Wallac Oy A Subsidiary of PerkinElmer, Inc.
c/o Ms. Susan K. Hamann
Regulatory Affairs Manager
940 Winter Street
Waltham, MA 02451

JUN 10 2011

Re: k110274
Trade Name: AutoDELFIA® Neonatal IRT Kit
Regulation Number: 21 CFR 862.1725
Regulation Name: Trysin test system.
Regulatory Class: I exempt, exceeds the limitation to exemption in 862.9(c) (2)
Product Codes: JNO
Dated: May 05, 2011
Received: May 06, 2011

Dear Ms. Susan K. Hamann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): _____

Device Name: **AutoDELFIA Neonatal IRT kit (B005-212)**

Indications for Use:

The AutoDELFIA Neonatal IRT kit is intended for the quantitative determination of human immunoreactive trypsin(ogen) (IRT) in blood specimens dried on filter paper as an aid in screening newborns for cystic fibrosis using the 1235 AutoDELFIA® automatic immunoassay system.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110274